REMARKS

Claims 48-63 were pending before this Response. By the present communication, claims 48, 59, 60 and 63 have been amended, and claim 53 has been cancelled. Accordingly, claims 48, 49, 52 and 54-63 are currently pending. Applicant respectfully requests entry and consideration of this amendment.

Rejection Under 35 U.S.C. § 112, First Paragraph

Applicant respectfully traverses the rejection of claims 48, 49 and 52-63 under 35 U.S.C. § 112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to convey that the Applicant was in possession of the claimed subject matter at the filing of the application. By the filing of this paper, Claim 53 has been canceled, rendering the rejection moot as pertains to this claim.

Applicant submits that the claims have been amended to recite that the methods for obtaining a protein having an activity of interest are now focused on use of genomic DNA from a plurality of organisms derived from an environmental sample. Throughout the Specification, enzymes are used as an illustration of how the screening of a gene expression library can be used to obtain proteins "having an activity of interest" by detecting the presence of the activity of interest produced by one or more constructs in the gene library.

Example 2 of the Specification provides a "representative example" of the procedure used for screening an expression library for enzymatic activity in "Tiers", proceeding from hydrolase in Tier 1 to amide, ester and acetal in Tier 2, to differences between individual substrates covalently attached to the functionality of Tier 2 in Tier 3, and possible enantiomeric products that an enzyme may produce from a substrate in Tier 4. Table 1 of the Specification provides substrates that can be used to screen for the various enzyme activity classes (types of amide hydrolase) of Tier 3 that are shown in Figure 1 of the Specification (i.e., terminal amidase, cyclic amidase, acylase and peptidase). Where the recombinant clone from the library is identified in Tier 2 as providing an ester, the Specification in Figures 2 and 3, shows the various substrates to be used for testing for various functionalities of the ester identified in Tier 2 by

reference to the compounds whose structures are shown in Tables 2, 3 and 4. Further, the compounds whose structures are shown in Table 5 may be used for testing to provide a protein having any of the Tier 3 activities shown in Figure 3. Thus, Applicant respectfully submits that those of skill in the art would have an understanding upon reading the Specification that the Applicant was in possession of the concept of using the disclosed method for the purpose of obtaining a protein, such as an enzyme, that has an activity of interest. Furthermore, Applicant submits those of skill in the art would understand that the Applicant conceived of the method as a general method that is not restricted to providing a single protein or enzyme having an activity of interest.

Thus, Applicant submits that those of skill in the art, upon reading the Specification, would understand how to obtain proteins with activities of interest. Consequently, Applicant was in possession of the invention, as defined by amended claims 48, 49, 52 and 54-63, at the filing of the application. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C. § 102(b)

Applicant respectfully traverses the rejection of claims 48, 49 and 52-63 for allegedly being anticipated by "the commercial availability of numerous natural products . . . " (Office Action, page 4). Applicant submits that the invention proteins having an activity of interest, as defined by amended claim 48, distinguish over the numerous natural products that are commercially available by the method of their obtaining, which method comprises:

a) culturing a gene expression library comprising a pool of expression constructs, each expression construct comprising one genomic DNA fragment, wherein the genomic DNA fragments in the pool of expression constructs are derived from a plurality of species of donor organisms derived from an environmental sample; and

b) screening the expression constructs to identify one or more expression construct containing a vector that produces a protein activity of interest;

c) removing the genomic DNA fragments from the one or more expression construct identified in b); and

d) expressing the DNA encoding the protein of interest, thereby obtaining the protein having an activity of interest.

As amended, the claims obtain proteins having activities of interest by expressing the genomic DNA from a plurality of organisms derived from an environmental sample. Applicant submits that linking the genomic DNA of the plurality of organisms to the obtained proteins avoids the "commercial availability of numerous commercial enzymes such as subtilisines, lipases, protein kinases, oxidases and glucosidases," as set forth by the Examiner on page 2 of the Advisory Action of October 20, 2004. Applicant cannot fathom a commercially available protein that is produced from the genomic DNA of organisms obtained from an environmental sample. Expression of the same genomic DNA sequence will yield the same unique protein each time. As such, Applicant submits that the expressed protein is linked to the genomic DNA that is to be expressed. Thus, a different unique protein will be expressed each time the genomic DNA from the plurality of organisms is obtained. These unique proteins are not commercially available.

The Examiner alleges that "the claimed protein invention is a chemical compound that is not described in the specification by any physical or chemical properties, and therefore can't be distinguished from many commercially available proteins and enzymes." (Advisory Action, page 3). Applicants submit that the claimed invention teaches the skilled artisan to obtain proteins having activities of interest from the genomic DNA of a plurality of organisms derived from an environmental sample. The physical and/or chemical properties of the subject proteins are unknown variables to be determined by the skilled artisan when practicing the invention. As

discussed above, the specification teaches how to select for an activity of interest, then obtain the relevant protein from the genomic DNA. The protein so obtained will be novel due to the characteristics of the genomic DNA expressed. Thus, the chemical properties of the protein obtained by the invention are determined by the skilled artisan upon using the invention.

Accordingly, Applicant submits that the numerous commercially available enzymes and proteins cited by the Examiner do not anticipate Applicant's invention, and respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Enclosed is Check No. 573218 in the amount of $395.00 for the RCE filing fee, and Check No. 573233 in the amount of $1,080.00 for the Five (5) Months Extension of Time fee. The Commissioner is hereby authorized to charge for any additional required fees, or credit any overpayments to Deposit Account No. 07-1896.

Respectfully submitted,

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